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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,326	11/03/2003	Sanford D. Damasco	ENDO108-C1-CP2CP	5138

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EXAMINER

KHOLDEBARIN, IMAN K

ART UNIT	PAPER NUMBER
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3709

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/700,326

Applicant(s)

DAMASCO ET AL.

Examiner

I Kenneth Kholdebarin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 04/05/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Objection

1. Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim is further limiting the ablation cycle of claim 19 not the treatment region of patient.
2. Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim is further limiting the steps of starting a freeze cycle for said first posterior lateral cryoprobe and said second posterior lateral cryoprobe of claim 19 rather than the treatment guidance plan.
3. Claims 22 - 23 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim is further limiting the ablation cycle of claim 17 rather than the treatment region of patient.

4. Claims 26-32 and 35 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim is further limiting the method of computer guided ablation of tissue of a patient cited in claim 25 rather than the system of claim 20 cited by the applicant.

5. Claim 33 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim is further limiting the method of treatment guidance plan of claim 31 rather than the method of ablative device with radio frequency.

6. Claim 34 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim is further limiting the method of ablation cycle rather than the method of ablative device with at least one laser fiber.

7. Claim 30 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 29. When two claims in an application are duplicates or else are so close in content that they both

cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 17, 19-23, 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Re Claims 19, 22 and 23: Claims 19, 22 and 23 recite the limitation "said ablation cycle" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Re Claim 20: Claim 20 recites the limitation "said step of starting a freeze cycle for said first anterior cryoprobe and said second anterior cryoprobe" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

Re Claim 21: Claim 21 recites the limitation "said step of starting a freeze cycle for said first posterior cryoprobe and said second posterior cryoprobe" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

Re Claims 26-29: Claims 26-29 recite the limitation "step of operating at least one ablative device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 31 recite the limitation "step of receiving imaging output data" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Re Claim 32: Claim 32 recites the limitation "step of providing a treatment guidance" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Re Claims 17 and 19-23: These claims comprise the apparatus and method together in the body of the claims. These are hybrid claims and should be clarified as to whether they are drawn to the apparatus or the method.

Appropriate correction is required.

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-3 and 7-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of Damasco, (U.S. 6,643,535).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claimed invention is somewhat broader recitation of the '535 patent, for example, in claim 1 of present claimed invention and claim 1 of '535 Patent, the Applicants claim:

“A system for providing computer guided ablation of tissue of a patient, comprising:

a. an imaging device for receiving imaging data from a treatment region of a patient, processing said imaging data and providing imaging output data and imaging signals, said imaging output data being available to an operator;

b. an ablative surgical computer system, comprising:

i) a guidance module for processing said imaging signals and providing a treatment guidance plan to the operator; and,

ii) a treatment module for acquiring and processing surgical device output data, for optimally

controlling treatment parameters and providing feedback information to the operator based on said treatment guidance plan; and,

c. a set of surgical devices, said set of surgical devices providing said surgical device output data, comprising:

i) at least one ablative device for providing ablation of said treatment region based on said treatment parameters and operator input; and,

ii) at least one temperature sensing device integrally attached to said at least one ablative device for acquiring temperature data from said treatment region and providing a temperature sensing device output signal, said temperature sensing device output signal being a portion of said surgical device output data wherein said treatment guidance plan is utilized for placing said at least one ablative device and said at least one temperature sensing device into said treatment region.”

In reference patent ‘535 stated:

“A system for providing computer guided ablation of tissue of a patient, comprising:

a. an imaging device for receiving imaging data from a treatment region of a patient, processing said imaging data and providing imaging output data and imaging signals, said imaging output data being available to an operator;

b. an ablative surgical computer system, comprising:

i) a guidance module for processing said imaging signals and providing a treatment guidance plan to the operator; and,

ii) a treatment module for acquiring and processing surgical device output data, for optimally controlling treatment parameters and providing feedback information to the operator based on

said treatment guidance plan; and,

c. a set of surgical devices, said set of surgical devices providing said surgical device output data, comprising:

- i) at least one ablative device for providing ablation of said treatment region based on said treatment parameters and operator input; and,
- ii) at least one temperature sensing device for acquiring temperature data from said treatment region and providing a temperature sensing device output signal, said temperature sensing device output signal being a portion of said surgical device output data wherein said treatment guidance plan is utilized for placing said at least one ablative device and said at least one temperature sensing device into said treatment region”, (See Col.8 line 14-43).

Therefore, in respect to above discussions, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a temperature sensing device as an element of a set of surgical device, and further being integrally attached within the set of surgical device with the ablative (Cryoprobe) device, to determine the temperature at the region where the ablative device will be used intra-operative as a cooling system and claimed by the present applicaiton. The instant claims obviously encompass the claimed invention of '535 Patent and differ only in terminology. To the extent that the instant claies are broaden and therefore generic to the claimed invention of '535 Patent, In re Goodman 29 USPQ 2d 2010 CAFC 1993, states that a generic claim cannot be issued without a terminal disclaimer, if a species claim has been previously been claimed in a co-pending application.

Re Claim 2 and 3: With respect to “thermocouple being extendible from a distal portion of said

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cannula to project outwardly from said cannula", it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the thermocouple being attached to ablative device and extendible from the distal portion of cannula at a desired distance, in order to monitor the temperature on surrounding tissue to prevent damaging of dropped temperature / freezing by cryoprobe or ablative device (38).

11. Claims 4-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of Damasco (U.S. Patent No. 6,643,535) in view of Zupkas (US 5,672,172).

Re Claims 4-6: However, Damasco fails to disclose or fairly suggest the ablative device with a fluid supply line with about 90 degrees angle.

Zupkas teaches at least one integrated ablative device with a fluid supply line connectable at an inlet section (15) to a source of cryogenic fluid; and a fluid connector assembly securely connected to an outlet section (16) of said fluid supply line for receiving fluid from said outlet section of said fluid supply line, said fluid connector defining a main connector assembly axis; and, a detachable cryosurgical probe (11) / which is obvious to one ordinary skill in the art for the repeated use in the surgery to be detachably connectable to said fluid connector assembly, and said cryosurgical probe (11) for receiving fluid from said fluid connector assembly and manipulating said fluid to provide suitable temperatures for cryosurgical treatment, (See Col.7, L 29-49) said detachable cryosurgical probe defining a probe axis, said main connector assembly axis and said probe axis being at a relative angle of about 90 degrees to each other. Zukaps

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teaches in Fig. 8 the relative angle of about 90 degrees of the probe and the connector fluid tubes and temperature-sensing device being integrally attached to the detachable cryosurgical probe.

Therefore, in view of Zukaps, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace fluid connector claimed by Damasco at the angle of 90 degrees with the fluid connector assembly comprising inlet (15) and outlet section (16) of said fluid supply line for receiving fluid from said outlet section of said fluid supply line at a relative angle of about 90 degrees in order to assist the surgeons and physicians with safer and more effective tools for treatment the patients with the ablative device into the body of a host for and accessing the treatment region and manipulating the tissues of the host.

Allowable Subject Matter

12. Claims 1-35 would be allowable over the prior art of record by timely filing terminal disclaimer.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art made of record and not relied upon is considered pertinent to applicants disclosure. Dowlatsahi discloses apparatus for interstitial laser therapy having an improved temperature sensor for tissue being treated; Edwards discloses self-contained power supply and monitoring station for RF tissue ablation; Dees discloses treatment of pigmented tissues using optical energy; Gough discloses

multiple antenna ablation apparatus and method; Motamedi discloses apparatus for emitting therapeutic energy within tissue.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to I Kenneth Kholdebarin whose telephone number is 571-270-1347. The examiner can normally be reached on M-F, from 8:00 am to 4 pm.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jong-Suk (James) Lee can be reached on 571-272-7044. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IKK

1/16/2007


JONG SUK LEE
SUPERVISORY PATENT EXAMINER